

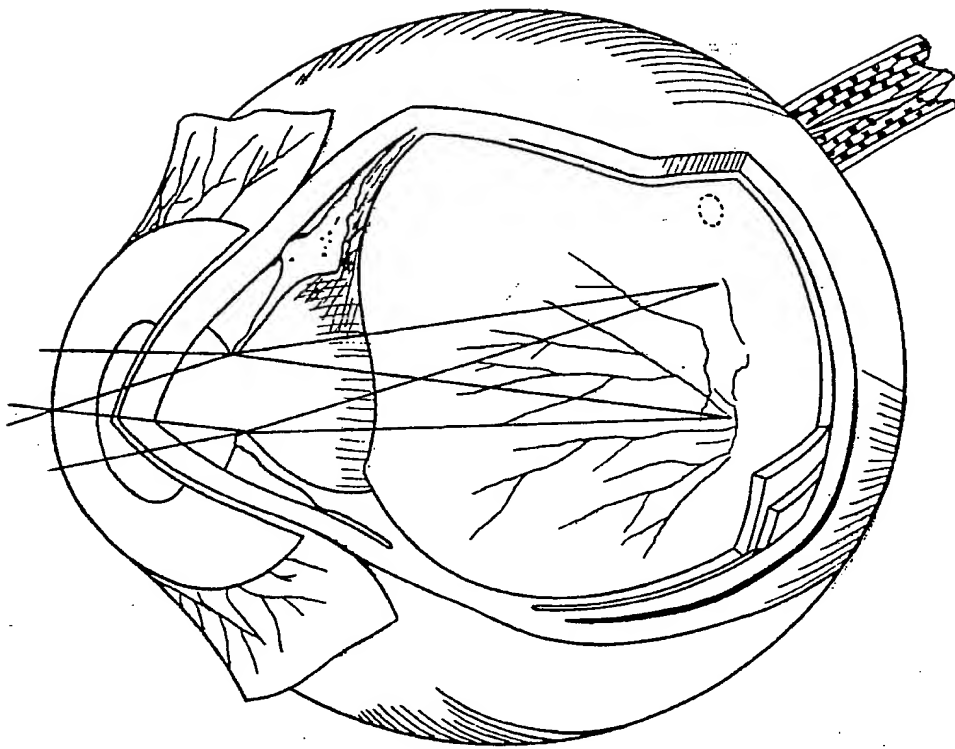
- (21) Application No 7935646
(22) Date of filing 13 Oct 1979
(43) Application published
17 Jun 1981
(51) INT CL³
A61K 31/495 33/14
(52) Domestic classification
A5B 170 230 23Y 272
274 27Y 38Y 39X 462 465
46Y 542 54Y 566 56Y J
(56) Documents cited
None
(58) Field of search
A5B
(71) Applicants
Welsh National School of
Medicine
Heath Park, Cardiff,
Glamorgan. CF4 4XN
(72) Inventors
Stuart Arthur Hodson
Malcolm Vaughan
Graham
(74) Agents
Wynne-Jones, Lainé &
James
Morgan Arcade
Chambers, 33, St. Mary
Street, Cardiff, Glam. CF1
2AB

(54) Intra-ocular irrigation fluid

(57) An intra-ocular irrigation fluid for replacing the aqueous humour of the eye, comprises an aqueous solution containing sodium chloride, potassium chloride, calcium chloride and N - 2 - Hydroxyethylpiperazine - N - 2 - ethanesulphonic acid. Sodium hydroxide may be included to establish a pH value of about 7.25 and magnesium sulphate may also be included.

2064320

1/1



SPECIFICATION

Intra-ocular irrigation fluid

5 If the front of the eye is opened by surgery the aqueous humour tends to spill out and must be replaced by some artificial pharmacologically prepared fluid. In some operations large quantities of fluid must be flushed through the orb.

10 Existing fluids used for the purpose have a deleterious effect on the endothelial cells of the cornea which line the posterior surface of the cornea and which are in intimate contact with fluid.

15 It is an object of the invention accordingly to provide an improved irrigation fluid for this purpose.

Broadly stated, the invention consists in an intra-ocular irrigation fluid comprising an aqueous solution containing sodium chloride .6-.8%; potassium chloride .01-.05%; calcium chloride .005-.04%; N - 2 -

20 Hydroxyethylpiperazine - N' - 2 - ethanesulphonic acid .2-.5% and sodium hydroxide sufficient to establish pH value 7.1 to 7.45.

According to a preferred feature of the invention the intra-ocular irrigation fluid also includes anhydrous dextrose up to 0.2%. It is also preferred that the intra-ocular irrigation fluid includes magnesium sulphate .7H₂O in the range up to 0.1%. The fluid may also include disodium hydrogen phosphate in a quantity of about .8 ml per litre of the solution.

30 The main active ingredients are sodium and potassium salts and the stated acid, which maintain cellular integrity. The calcium salts maintain intercellular cohesion.

The particular preferred formula for the solution is as follows:

35	Sodium Chloride	0.7046%
	Potassium Chloride	0.0298%
	Magnesium Sulphate .7H ₂ O	0.0247%
	Anhydrous Dextrose	0.0802%
40	Calcium Chloride .2H ₂ O	0.0373%
	** N-2-Hydroxyethylpiperazine	0.4766%
	-N'-2-ethanesulphonic acid	
	Sodium Hydroxide	0.0264%

45 The pH should be adjusted to approximately 7.25 ± 0.02

** Referred to for convenience as N-2-H-N'-2-e

50 This solution should be sterilised by standard autoclaving techniques in any inert container. Immediately before use 0.8 ml of sterilised disodium hydrogen phosphate strength 17.75% should be added to one litre of the main solution.

55 The accompanying drawing is a diagrammatic perspective view of the human eye, partly sectioned to show the various internal constructions.

The transparency of the cornea is regulated by a biological pump located in the endothelial cells of the cornea. The activity of the pump may be monitored by measuring the electrical signals associated with its action. Additionally investigations into the electrical properties of the cornea may be used to measure the cohesion between the endothelium cells. Therefore by measuring the electrical properties of the corneal endothelium, it is possible to

monitor any traumatic responses in either their biological pump which regulates corneal transparency or in their structural integrity. The intra-ocular replacement fluid of the present invention has been found to cause no measurable irreversible deterioration of the corneal endothelium.

CLAIMS

1. An intra-ocular irrigation fluid comprising an aqueous solution containing sodium chloride .6-.8%; potassium chloride .01-.05%; calcium chloride .005-.04%; N - 2 - Hydroxyethylpiperazine - N' - 2 - ethanesulphonic acid .2-.5% and sodium hydroxide sufficient to establish pH value 7.1-7.45.

2. An intra-ocular irrigation fluid according to claim 1, including also anhydrous dextrose up to 0.2%.

3. An intra-ocular irrigation fluid according to claim 1 or claim 2, including magnesium sulphate .7H₂O in the range up to 0.1%;

85 4. An intra-ocular irrigation fluid according to any of the preceding claims, including sterilised disodium hydrogen phosphate in a quantity of about .8 ml per litre of the solution.

5. An intra-ocular irrigation fluid substantially as described herein.

6. A method of replacing, flushing out, or topping up, the aqueous humour of the eye, using an irrigation fluid in accordance with any of the preceding claims.

Printed for Her Majesty's Stationery Office by The Tweeddale Press Ltd., Berwick-upon-Tweed, 1981.
Published at the Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.

THIS PAGE BLANK (USPTO)